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A LIMITED LIABILITY PARTNERSHIP

October 18, 2019

VIA ECF

The Honorable Colleen McMahon
United States District Judge
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, NY 10007

**Re: *In re Namenda Direct Purchaser Antitrust Litigation*, 15-CV-07488-CM-RWL
Letter Brief in Response to Order, ECF No. 887**

Dear Judge McMahon:

Forest submits this letter brief in response to the Court’s request for briefing on the issues of (1) “large in relation to what,” and (2) whether Forest’s privilege election bears on that analysis.

Consistent with the broad lens of the rule of reason, courts have routinely held that whether a payment is large and unexplained must be measured in relation to all the facts and circumstances of a case. Beyond the considerations expressly mentioned in *Actavis* (avoided litigation costs and fair value for services), courts have allowed consideration of the profits of the branded medication, which, when compared to the alleged payment, provide objective evidence of whether the brand and generic viewed the payment as designed to protect a weak patent. Indeed, in the *Apotex* reverse payment case—which Plaintiffs cited in their proposed jury instruction on largeness (No. 50)—defense counsel was permitted to present precisely this type of argument in closing: “What does Dr. Bell have to say? If you have got the power to take 5 billion of profits away from [the brand], I don’t understand why you agree to that just for 25.8 million. . . . That is common sense.” Trial Tr. 31:12-32:4, *Apotex, Inc. v. Cephalon, Inc.*, No. 06-cv-02768 (E.D. Pa. July 6, 2017) (Ex. A).

Courts have therefore held that it is appropriate to consider the perspective of *both the brand and the generic*, including the information that would bear on each side’s perspective in settlement negotiations. It is impossible to determine if an alleged payment reflects traditional settlement considerations by looking at only one side’s perspective, as Plaintiffs suggest.

That is why, to our knowledge, no court has limited a jury to considering *only* whether the payment is large from the generic’s perspective.

On the second question, Forest’s privilege election means that it cannot rely on its subjective beliefs about its position in the patent case. *See* Ruling on DPP MIL No. 1 (ECF No.

859). But nothing about that election changes the analysis above or precludes Forest from defending itself by relying on objective facts—particularly those known to both Forest and Mylan during their negotiations, such as Forest’s profits on Namenda. Indeed, defendants in several of the cases cited below presented objective evidence about how the alleged payment compared to brand profits while also declining to assert their subjective beliefs at trial.

1. Whether A Payment Is “Large And Unexplained” Is Measured In Relation To All Relevant Facts And Circumstances.

The rule of reason requires an evaluation of the alleged anticompetitive conduct in light of “all of the circumstances of a case,” including relevant business considerations. *Bd. of Trade of the City of Chi. v. United States*, 246 U.S. 231, 238 (1918); *see also, e.g., Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877, 885 (2007) (“Under [the rule of reason], the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited,” including “specific information about the relevant business”) (quotations omitted); *MLB Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 316-17 (2d. Cir. 2008) (“[T]he rule of reason requires the factfinder to decide whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint on competition”).

Courts in reverse payment cases thus have rejected plaintiffs’ efforts to limit the evidence juries can consider in determining whether an alleged payment is “large and unexplained.” For example, one court denied plaintiffs’ motion *in limine* to “narrow the evidence at trial as to whether [an alleged reverse payment] was ‘large,’” concluding that “whether a reverse payment [is] ‘large and unjustified’ . . . requires viewing the payment in its factual context, which may include certain business realities.” Text Order, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-MD-2503 (D. Mass. Mar. 8, 2018) (Ex. B) (citation omitted); *see* Order at 2, *Apotex, Inc. v. Cephalon, Inc.*, No. 06-cv-02768 (E.D. Pa. July 5, 2017) (Ex. C) (denying plaintiffs’ motion *in limine* to preclude argument about “business reasons” for settlement); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015) (motion to dismiss order finding that “payments smaller than avoided litigation costs are presumptively not large” but “payments exceeding avoided litigation costs are not automatically deemed unlawful for that reason alone”); *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 416 (E.D. Pa. 2015) (summary judgment order concluding that “*Actavis* did not identify any specific formula for determining whether a reverse payment is sufficiently large.”).

Likewise, courts instructing juries in reverse payment cases have rejected plaintiffs’ efforts to reduce the question whether an alleged payment is “large and unexplained” to narrow formulas such as comparisons to avoided litigation costs or potential generic profits. Instead, consistent with *Actavis*, these courts have told juries that whether a payment is large and unexplained “depends upon the specific circumstances of a particular case.” Trial Tr. 44:10-11, *In re: Nexium Antitrust Litig.*, 12-md-02409 (D. Mass. Dec. 3, 2014) (Ex. D); *see also* Trial Tr. 38:4-5, *Apotex, Inc. v. Cephalon, Inc.*, 2:06-cv-02768 (E.D. Pa. July 5, 2017) (Ex. E) (“Whether a payment is large depends on the specific facts and circumstances of this case.”).

It is therefore unsurprising that courts have also allowed juries to consider the size of a

payment relative to the brand's profits:

- In *Apotex v. Cephalon* (mentioned above), the court permitted defendants' expert to testify—and defense counsel to argue in closing—that a \$25.8 million payment was not large and unexplained in light of the fact that the brand's profits on the drug were \$5 billion, because common sense dictates that a generic would not settle for only \$25.8 million if it had the power to take \$5 billion away from the brand by continuing its patent challenge. Ex. A, Trial Tr. 31:12-32:4 (Defense counsel: "What does Dr. Bell have to say? If you have got the power to take 5 billion of profits away from [the brand], I don't understand why you agree to that just for 25.8 million. . . . That is common sense.>").
- In *Barba v. Shire US, Inc.*, the Magistrate Judge recommended that the district court reject plaintiffs' challenge to an expert's testimony that "emphasizes an analysis of 'largeness' based on the brand's perspective" because "it [is] essential to compare the alleged payment to the operating income of the brand derived from the drug at issue." No. 13-21158-CIV, 2016 U.S. Dist. LEXIS 182548, at *14 (S.D. Fla. Jan. 19, 2016).
- In the *Solodyn* litigation, the court denied plaintiffs' motion *in limine* seeking to exclude evidence and argument comparing the size of the alleged payment to the potential profits that defendants stood to lose if generic competitors entered the market. Ex. B at 4-5; *see also* Plaintiffs' Motion in Limine (12) to Preclude Improper Evidence & Arguments as to Whether the Reverse Payment to Impax Was "Large" at 1, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-MD-2503 (Ex. F).

Similarly, a district court ruling on a motion to dismiss concluded that whether the alleged payment "was a substantial amount of annual sales of the brand product may be an appropriate fact, as it must be a payment that appears to be large *from the perspective of the brand company making the payment.*" *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 U.S. Dist. LEXIS 142206, at *75 (D.N.J. Oct. 6, 2014) (emphasis added).

These cases reflect the importance of considering *both sides' perspectives* in evaluating whether an alleged payment is large and unexplained. Contrary to Plaintiffs' position, the Third Circuit has made clear that the brand's perspective must be considered. *See, e.g., King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp. (In re Lamictal Direct Purchaser Antitrust Litig.)*, 791 F.3d 388, 405 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016) (asking whether "the source of the benefit to the [generic] is something costly to the [brand]"); *see also In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 332 (D.R.I. 2017) ("The text of *Actavis* suggests that the Court should consider both [the perspective of the brand and the generic] in considering an alleged unlawful reverse payment."). Plaintiffs partially acknowledge the point in agreeing that the brand's avoided legal costs can be considered, Pls.' Proposed JI 50 (ECF 701). As the foregoing cases show, there is no legal support for ignoring the other considerations that might go into the brand's decision to settle.

Plaintiffs' suggestion that only the generic's perspective should be considered would also lead to absurd results. This case is a good example. Mylan stood to gain only \$690,000 if it

prevailed in the patent litigation. Under Plaintiffs’ approach, a payment of \$690,001 would have to be considered large because the payment would have induced Mylan to settle by providing more money than it would have earned had it prevailed in the patent case. It is absurd to think that such a payment would necessarily reflect a weak patent case as opposed to other relevant considerations, such as a desire for certainty or the avoidance of business disruption from litigation. *See FTC v. Actavis*, 570 U.S. 136, 156, 158 (2013).

Accordingly, the Court should reject Plaintiffs’ blinkered approach and allow the jury to consider all the facts and circumstances—including the relationship between the alleged payment and the branded profits as a proxy for patent strength—in determining whether Forest made a “large and unexplained” payment to Mylan.

2. Forest’s Assertion Of Privilege Does Not Alter The Framework For Deciding Whether An Alleged Payment Is Large And Unexplained.

Forest’s decision not to affirmatively rely on evidence of its subjective beliefs regarding the strength of its patent eliminates one potential source of evidence for the jury to consider, but otherwise does not alter the jury’s task in any way. As the Court has ruled, Forest will be limited to presenting only objective facts about its position in the patent cases. *See Order on Plaintiffs’ MIL 1* (ECF 859). Aside from that limitation, nothing about Forest’s election affects the jury’s analysis of whether Forest made a large and unexplained payment or the evidence the jury may consider. Indeed, several of the defendants in the cases cited above made arguments about the alleged payment from both sides’ perspective despite also making a similar election not to waive the attorney-client privilege. *See, e.g., Apotex, Inc. v. Cephalon, Inc.*, No. 06-cv-02768, 2017 U.S. Dist. LEXIS 82727, at *11-12 (E.D. Pa. May 31, 2017) (allowing defendants to present “non-privileged evidence” of the “legitimate considerations [that] motivated their decision to settle” “despite their invocation of the attorney-client privilege”); *see supra* at 2-3 (defense attorney’s closing argument comparing alleged payment to brand profits); *King Drug v. Cephalon, Inc.*, No. 06-cv-1797, 2016 U.S. Dist. LEXIS 7477, at *25-26 (E.D. Pa. Jan. 22, 2016) (similar).

The jury should therefore be free to consider the litigation costs avoided by both parties, Mylan’s expected profits from generic Namenda, and Forest’s profits from branded Namenda. These and other objective facts bear on what the parties’ settlement says about the patent case, which is the ultimate question the jury must decide.

Respectfully submitted,



Beth Wilkinson